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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,962	01/26/2004	Helga Biergiesser	104035.273254	5690

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EXAMINER	
HARLE, JENNIFER I	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/767,962	BIERGIESSER ET AL.	
	Examiner	Art Unit	
	Jennifer I. Harle	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,15-18 and 34-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,15-18 and 34-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-32 were pending and subject to and Election/Restriction Requirement. Claims 1-13 and 15-18 are amended and 34-38 are newly added. Claim 14 is cancelled and claims 19-33 are withdrawn.

2. Thus, claims 1-13, 15-18 and 34-38 are pending.

Election/Restrictions

3. Applicant's election with traverse of Group I in the reply filed on March 14, 2005 is acknowledged. The traversal is on the ground(s) that the searching of each group would not impose an undue burden on the examiner. This is not found persuasive because the burden was clearly set forth in the Election/Restriction requirement and Applicant did not set forth any reasons why it would not be burdensome. Applicant's election of creatinine derivatives as a species is noted.

The requirement is still deemed proper and is therefore made FINAL.

4. Claims 19-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected groups, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the replies filed on March 14 and 17, 2005.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-13, 15-18, 34-35 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's amended claim1-13, 15-18 and added claims 34-35 and 36. The claims utilize the language creatine salts and creatine esters, however, the Specification does not disclose these subgenus of creatine derivatives. It does disclose creatine phosphate, creatine sulfate, creatine ascorbate and creatine acetate and creatine derivatives esterified on the carboxyl group with mono or poly-functional alcohols leading to advantageous embodiments in general. However, the salts are only four compounds and do not embrace the broad subgenus and the mono or poly-functional alcohols do not embrace the broad subgenus of all alcohols to encompass all esters nor does it provide structural guidance as to what alcohols are specifically included and excluded as it is defined by functionality and could be non-functional.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-11, 17-18, 36-38 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Howard, et al. (US 5,968,544), cited by Applicant.

The claims are drawn to a preparation comprising a content of an active ingredient combination, where the active ingredient comprises at lease one compound selected from the group consisting of creatinine and derivatives thereof in combination with a least one compound selected from the group consisting of creatine, creatine salts and creatine esters with intended use as cosmetic or dermatological preparations for treating various skin conditions.

The cited reference teaches a combination composition (including in creatine/creatine phosphate/creatine monophosphate/or any active form of creatine), which contains creatinine, as a converted related compound of creatine, as creatine is unstable and can be used to increase creatine in the human body, i.e. consisting of (or consisting essentially of) the same combination composition, which appears to be identical to (and thus anticipate) the presently claimed combination composition (including inherently comprising the instantly claimed present in an effective any amount would be effective given the fact that no amount is claimed, as well as the specific combination of creatinine and creatine and creatinine in combination with creatine phosphate claims 37 and 38, therein) since both were prepared using the same compounds and the instant patent contains higher ranges of the creatinine and creatine it would treat the dermatological conditions set forth (see entire document including columns 1-2, Examples 1 and 6, Figs. 1-6 and claims). Consequently, the instantly claimed combination composition appears to be anticipated by the cited reference.

In the alternative, even if the claimed combination composition is not identical to the referenced combination composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced combination composition is likely to inherently possess the same characteristics of the claimed combination composition particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed combination composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Further, if not anticipated, the result-effective adjustment of particular conventional working conditions (e.g., obtaining the active ingredient in an effective amount comprising a result-effective amount of the combination composition beneficially taught by Abeles therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether the levels of creatine/creatine derivatives and creatinine/creatinine derivatives within Applicant's combination composition differ and, if so, to what extent, from the levels within the combination composition disclosed by the cited reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

8. Claims 12-13, 15, 16, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard, et al. (US 5,968,544), cited by Applicant.

Howard discloses as set forth above. However, Howard does not discloses that the creatine or creatinine is present in the specific weight percents or weight ratios. The result-effective adjustment of particular conventional working conditions (e.g., determining appropriate amount ranges and/or dosage periods) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, based upon the beneficial teachings provided by the cited references, as discussed above. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to have adjusted the specific weight percents or weight ratios of creatine or creatinine and accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

9. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Howard, et al. (US 5,968,544), cited by Applicant in view of Cohn (US 5,576,316).

Howard, discloses as set forth above. However, Howard does not disclose that the creatine ester are present and selected from the group consisting of esters of creatine with mono- or poly functional alcohols. Cohn discloses that creatine (which is a well known substance in and of itself) analogs are compounds, which are structurally similar to creatine compounds which are art-recognized as being analogs of creatine and/or compounds which share the same or similar functions as creatine and include creatine salts and that the salts are capable of being hydrolyzed under under physiological conditions and is intended in included lower hydrocarbon groups capable of being hydrolyzed under physiological condition, i.e. groups which esterify the

carboxyl moiety, e.g. methyl, ethyl and propyl and that the analogs may be purchased or alternatively synthesized using conventional techniques because typically these salts are capable of being hydrolyzed under physiological conditions. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention that creatine salts would have included the esterified compounds, with mono- or polyfunctional alcohols, i.e. lower hydrocarbon groups of methyl, ethyl and/or propyl, as set forth in Cohn to create the ester that would already have been present.

10. Claims 1-6, 8-13, 17-18, 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaddurah-Daouk (US 6,242,491 B1) in view of Yu, et al. (US 5,883,128). Kaddurah-Daouk discloses the use of creatine, creatine phosphate or analogs of creatine for protecting skin tissue against age related damage or insults, harmful UV radiation, stress and fatigue and would include wrinkles, loss of elastisticity of the skin and uneven pigmentation of the skin, and even mitochondrial disfunction. Abstract, Col. 2, lines 15-28, col. 3, lines 19-25 and 43-52, col. 4, lines 1-14, Col. 8, lines 35-43, col. 14, lines 38-50, Claims 1, 6-9, 11-16, 18, 20, 25, 29-32. Additionally, Kaddurah-Daouk discloses that topical pharmaceutical compositions of the present invention may be contain from about 0.1% to about 50% of the active compound and from about 2% to about 50% of a topical pharmaceutically-acceptable emollient and if a lotion can comprise from about 0.1% to about 20% of the active compound. Col. 5, lines 45-65. Kaddurah-Daouk also discloses that the creatine compound may be used in skin cleaning compositions as an active ingredient. Col. 8, lines 10-16. Kaddurah-Daouk further discloses that the selected dosage level will depend upon a variety of factors including the activity of the particular compound of the present invention employed, or the ester, salt or amide

thereof, the route of administration, the time of administration , the rate of excretion of the particular compound being employed, the duration of the treatment, other drugs, compounds and/or materials sued ,etc. as is well known in the art. Col. 13, lines 56-67. Yu discloses that creatine and creatinine are individually active ingredients in treating skin disorders including dry skin acne dandruff, keratoses, psoriasis, eczema, pruritus, age spots, lentigines, melasmas, wrinkles, warts, blemished skin, hyperpigmented skin, hyperkeratotic skin, imflammtory dermatoses, skin changes associated with aging, disturbed keratinizationm, as skin cleansers, and aid in keeping and intact skin as an effective barrier and the weight percent of creatinine is between .1 and 10%. Abstract, cols. 1-5, col. 10, lines 33-40, Examples 4, 13, 19, 22, 25, 27, 29, 33, 37, Claims 1, 15 and 16. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

11. Claims 1-6, 8-13, 17-18, 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaddurah-Daouk (US 6,242,491 B1) in view of Yu, et al. (US 5,883,128).

Kaddurah-Daouk and Yu discloses as set forth above. However, Kaddurah-Daouk and Yu do not disclose that the creatine or creatinine is present in the specific weight ratio of 1:2 to 2:1 or that creatinine is present in an amount from 0.1% to 1% weight. The result-effective adjustment of particular conventional working conditions (e.g., determining appropriate amount ranges and/or dosage periods) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, based upon the beneficial

teachings provided by the cited references, as discussed above. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to have adjusted the specific weight percent or weight ratio of creatine or creatinine and accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

12. Claims 1-11, 18, 36-37 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Honda, et al. (4,970,072) or Gardlik, et al. (US 2002/0119174) in view of D. Venkatappaiah, et al. Nonprotein nitrogenous constituents of Milk. I. Variation due to species, breed, individuality, season, and stage of lactation, Indian Journal of Dairy Science, 1952, Vo. 5, pp. 95-116 (Abstract Only).

The claims are drawn to a preparation comprising a content of an active ingredient combination, where the active ingredient comprises at lease one compound selected from the group consisting of creatinine and derivatives thereof in combination with a least one compound selected from the group consisting of creatine, creatine salts and creatine esters with intended use as cosmetic or dermatological preparations for treating various skin conditions.

Honda discloses that people in Europe have traditionally added cow's milk to baths to exploit its beautifying and health promoting effects. Col. 1, lines47-49. Gardlik discloses that Cleopatra was known to immerse herself in luxuriant baths of milk and honey to revitalize her hair. It is an old an well known treatment to put butter on a burn and to take milk baths to treat the skin for anti-aging purposes, etc.. Venkatappaiah discloses that milk contains creatinine and creatine. Thus, the cited references inherent/implicitly disclose utilizing a combination composition, creatine/creatine, which appears to be identical to (and thus anticipate) the presently claimed

combination composition (including inherently comprising the instantly claimed present in an effective any amount would be effective given the fact that no amount is claimed, as well as the specific combination of creatinine and creatine since it was prepared from the same compounds it would treat the dermatological conditions set forth (see entire document including columns 1-2, Examples 1 and 6, Figs. 1-6 and claims). Consequently, the instantly claimed combination composition appears to be anticipated by the cited reference.

In the alternative, even if the claimed combination composition is not identical to the referenced combination composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced combination composition is likely to inherently possess the same characteristics of the claimed combination composition particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed combination composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether the levels of creatine/creatine are "within an effective amount" within Applicant's combination composition differ and, if so, to what extent, from the levels within the combination composition disclosed by the cited reference. Therefore,

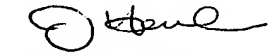
with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jennifer I. Harle
Examiner
Art Unit 1654

May 26, 2005